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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,769	10/20/2001	Randy D. McKinnon	268/260	5576
26259	7590	09/15/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/051,769	Applicant(s) MCKINNON, RANDY D.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/26/2002</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibits A-F</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-4, and 6-9 in the reply filed on 06/25/04 is acknowledged. The traversal is on the ground(s) that the restriction requirement of record does not meet the two criteria set out in MPEP § 803. The inventions have not been shown to be independent and distinct and the examination of all groups would not impose a serious burden on the examiner. This is not found persuasive.

MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the two groups are distinct for the reasons set forth in Paper mailed on 06/02/2004. As to the question of burden of search, the inventions are classified differently, necessitating different searches in the US Patent class/subclass. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. In the instant case, the search for the polynucleotides and the method of detecting whether a patient is at risk for progression into glioblastoma multiforme using a polynucleotide are not coextensive. The search for group II would require a text search for the method of detecting whether a patient is at risk for progression into glioblastoma multiforme in addition to the nucleic acid product search. Prior art, which teaches the claimed polynucleotides, would not necessarily be applicable to the method of using the claimed polynucleotides for detecting whether a

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patient is at risk for progression into glioblastoma multiforme. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps. Different searches and issues are involved in the examination of each group.

The requirement is still deemed proper and is therefore made FINAL.

Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/25/04.

Claims 1-9 are pending. Claims 1-4, and 6-9 are examined on merits.

Specification

The disclosure at pages 2, 12, and 14 of the specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification is also objected for the following reason: The “stringent conditions” are considered essential subject matter to the instant application and the claimed invention.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference (i.e. McKinnon et al., note page 5, line 11 of the specification). The amendment must be accompanied

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by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United states or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This written description rejection is made because the claims are interpreted as drawn to a genus i.e. any nucleic acid that minimally contains SEQ ID NO:2, or a sequence that hybridizes to SEQ ID NO:2 under stringent conditions.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The specification discloses that instant SEQ ID NO:2 is an EST. The present claims with the open transitional phrase "comprising" an EST encompass full-length genes and cDNAs that are not further described. There is a substantial variability among the species of cDNAs encompassed within the scope of the claims because SEQ ID NO:2 is only a fragment of any full-length gene(s) or cDNA species. They are structurally unrelated. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. A nucleic acid hybridizes to SEQ ID NO:2 or its complement also fails to provide adequate written description and evidence of possession of a claimed genus. The present claims do not identify a function associated with the partial structure of SEQ ID NO:2 or hybridizing molecules. Since the breadth of the claims as reading on genes yet to be discovered, the lack of correlation between the claimed structure and the function of the genes, it is concluded that the written description requirement is not satisfied

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the

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encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 2. Therefore, only isolated nucleic acid consisting of SEQ ID NO:2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claims 1-4, and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the claimed invention is interpreted as drawn to an isolated nucleic acid molecule comprising SEQ ID NO:2 or kit containing two primers i.e. SEQ ID NO:5, and 6 for use in detection of whether a patient is at risk for progression into glioblastoma multiforme, or other malignant phenotype.

The specification teaches that SEQ ID NO:2 is an EST sequence. The specification asserts that the claimed SEQ ID NO:2 and the two primers i.e. SEQ ID NOs:5, and 6 could be used in detection of whether a patient is at risk for progression into glioblastoma multiforme, or other malignant phenotype. The specification discloses that the claimed nucleic acid is expressed at high level in immortal glioblast cell lines. However, the specification does not disclose whether the claimed nucleic acid is overexpressed or underexpressed in glioblastoma multiforme tissue compared to the healthy tissue control. Since the nucleic acid is expressed at higher level in normal brain tissues, it is not clear how to use the claimed invention to evaluate whether a patient is at risk for progression into glioblastoma multiforme.

The amount of direction or guidance by the inventor how to use the claimed invention is limited. The quantity of experimentation needed to use the claimed invention is large. In order to use the claimed invention, one skilled in the art has to screen a large quantity of clinical samples to determine whether a differential SEQ ID NO:2 expression is correlated with glioblastoma multiforme, or other malignant phenotype.

Cancer diagnosis and prognosis art using a new marker is unpredictable. Since the specification does not disclose that an altered levels or forms of the claimed nucleic acid is associated with glioblastoma multiforme, or other malignant phenotype in vivo as compared with the corresponding healthy tissue, one of skill in the art would have reason to doubt that the instantly claimed SEQ ID NO:2, 5, and 6 could be used in a method of identifying a patient at risk for progression into the malignant phenotype, or

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glioblastoma mutiforme. McKinnon et al. (IDS AP filed on 03/26/2002, J. Cell Biology, vol. 85, pages 890-902) at the last sentence of abstract teach that a marker expression of in vitro cells such as immortalized cultured cells may not be a very useful indicator of what the expression pattern would be in the counter-part in vivo cells because the tight regulation of expression is lost in cells in culture.

Tockman et al., (Cancer Res., 1992, 52:2711s-2718s) teach that cancer diagnosis or prognosis is an unpredictable art. The specification does not provide in vivo data that a patient at risk of progression into glioblastoma multiforme has an altered expression of the claimed nucleic acid. Tockman et al., teach considerations necessary in bringing a cancer biomarker to successful clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to the instant invention. Tockman et al teach that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of tumorigenicity have clear biological plausibility as markers of preclinical cancer and if validated can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and link those marker results with

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subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). Likewise, Fujisawa et al., (American Journal of Pathology, vol. 155, pages 387-394) teach a new marker for glioblastoma (a malignant type of brain tumor) phenotype detection has to be validated against acknowledged disease end points. Fujisawa et al., teach that in order to use a new marker for detection of glioblastoma, it is necessary to examine the clinical samples from patients who have glioblastoma.

Since the instant specification does not teach any differential expression or a mutated form of the instantly claimed nucleic acid in patients with glioblastoma or any other malignant phenotype, one of skill in the art has to screen a large quantity of clinical samples from brain tumor patients. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed invention, it is concluded that undue experimentation is required to practice the invention.

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Further, claim 2 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The limitation "under stringent condition" critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In order to practice the invention claimed in claim 2, one of skill has to know the claimed stringent conditions incorporated by reference. Note the objection to the specification above. An amendment accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application would obviate this part of rejection. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. Claim 3, as written, does not sufficiently distinguish over nucleic acids as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*,

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447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claims 1-4, and 6-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

The disclosed utilities for the claimed nucleic acids are to diagnose and treat brain cancer including glioblastoma (note the paragraph bridging pages 2 and 3 of the specification).

The specification discloses that the claimed nucleic acid is expressed at high level in immortal glioblast cell lines, as well as brain cortex, liver, thymus, or kidney cells, while expressed at lower levels in testis. Since the specification does not disclose that the claimed nucleic acid is over-expressed in in vivo glioblastoma or any other in vivo brain tumors, the asserted use of the claimed invention in diagnosis of brain tumor including glioblastoma is not substantial. The specification does not disclose whether the claimed nucleic acid is overexpressed or underexpressed in a specific, diseased tissue compared to the healthy tissue control.

The overexpression in immortal glioblast cell lines is not considered to be substantial either because this disclosure does not lead to substantial use of the claimed invention in diagnosis of a brain tumor. The art acknowledges that the characteristics of cultured cell lines generally differ significantly from the characteristics of in vivo primary cancers or metastatic cancers. Freshney (Culture of Animal Cells, A

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Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, page 4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*). Further, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Further, Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary -type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not, yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years.

The specification discloses that the instantly claimed nucleic acid encodes a protein that shares sequence homology with a gene product of *Drosophila* (page 3). However, the art generally acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. Scott et al (Nature

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Genetics, 1999, 21:440-443) teach that the function of newly identified gene products is unpredictable even when the database searches reveal significant homology to proteins of known function. Scott et al teaches that the gene causing Pendred syndrome encodes a putative transmembrane protein designated pendrin. Based on sequence similarity data, the authors postulated that the putative protein was deemed to be a member of sulfate transport proteins that included a 29% identity to rat sulfate-anion transporter, 32% similarity to human diastrophic dysplasia sulfate transporter, and 45% similarity to the human sulfate transporter 'downregulated in adenoma'. However, upon analyzing the expression and kinetics of the protein, the data revealed no evidence of sulfate transport wherein results revealed that pendrin functioned as a transporter of chloride and iodide. Scott et al. states that these results underscore the importance of confirming the function of newly identified gene products even when the database searches reveal significant homology to proteins of known function (page 411, 1st column, 4th paragraph). Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (2000, Genome Research 10:398-400) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks et al. (1998, Trends in Genetics 14:248-250) who state that (1) functional information is only partially annotated in the database, ignoring multi

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functionality, resulting in underpredictions of functionality of a new protein and (2) overpredictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith et al. (1997, Nature Biotechnology 15:1222-1223) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions. Bork et al. (1996, Trends in Genetics 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts. Finally, Bowie et al. (1990, Science 247:1306-1310) state that determination of three dimensional structure from primary amino acid sequence, and the subsequent inference of detailed aspects of function from structure is extremely complex and unlikely to be solved in the near future (p. 1306). Thus, the specification fails to support the asserted credible, specific and substantial utility of the newly identified instantly claimed nucleic acids.

In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), the court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. §

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101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to nucleic acid, which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the claimed nucleic acids, the claimed invention is incomplete.

Claims 1-4, and 6-9 also are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,673,549 (06 January 2004, with the effective filing date of 12 October 2000).

Claims 1-4, 6, and 7 are interpreted as drawn to an isolated nucleic acid comprising SEQ ID NO:2 (or comprising a sequence hybridizes to the complement of

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SEQ ID NO:2), wherein said nucleic acid is labeled with various art-known labels (claim 4), wherein said nucleic acid is in a kit with instruction for use (claims 6, and 7).

US 6,673,549 in claim 1 teaches an isolated nucleic acid i.e. SEQ ID NO: 899 comprising instant SEQ ID NO:2 (comprising a sequence hybridizes to the complement of SEQ ID NO:2). Note Exhibit A (sequence alignment). US 6,673,549 also teaches that the nucleic acid is in a kit i.e. a microarray (note column 28). According to Merriam-Webster online dictionary downloaded on 8/16/04 from [url>>>www.m-w.com](http://www.m-w.com), "kit" is defined as collection of articles. Thus, the nucleic acid comprising instant SEQ ID NO:2 in the collections of cDNA in a microarray is in a kit. Further, US 6,673,549 teaches how to use the nucleic acid in cDNA microarray for expression profiling purposes and other instructions for uses at columns 14 to 17. US 6,673,549 teaches various reagents including radioisotope and other labels, and other components in performing assays at columns 13-17. As for claims 3, 4, 6, and 7, the preamble recitation of use in identifying a patient at risk for progression into the malignant phenotype or detecting whether a patient is at risk for progression into glioblastoma multiforme is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the nucleic acid *per se*.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank accession number AC005887 (05 November 1999).

Claims 1-3 are interpreted as drawn to an isolated nucleic acid comprising SEQ ID NO:2.

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GenBank accession number AC005887 teaches an isolated nucleic acid that matches 100 % to instant SEQ ID NO:2. Note the attached Exhibit B (sequence alignment). As for claim 2, since GenBank accession number AC005887 matches 100 % to the instant SEQ ID NO:2, it would hybridizes to the complement of SEQ ID NO:2. As for claim 3, the preamble recitation of use in identifying a patient at risk for progression into the malignant phenotype is merely suggestive of an intended use and is not given patentable weight for purposes of comparing the claim with the prior art. The claim reads on the nucleic acid *per se*.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by either US 5,759,811 (02 June 1998) or GenBank Acc. No AW013379 (10 September 1999).

Claim 2 is drawn to a nucleic acid comprising a sequence hybridizes to the complement of SEQ ID NO:2.

US 5,759,811 teaches SEQ ID NO:5 at columns 21-24, and claims 4, and 16, wherein nucleotides #988 to 1008 of SEQ ID NO:5 (total 21 nucleotides) match 100 % with nucleotides # 139 to #159 of the instant SEQ ID NO:2. See Exhibit D (sequence alignment).

GenBank Acc. No AW013379 teaches a nucleic acid molecule that matches 100 % to the nucleotides #1 to 42 of the instant SEQ ID NO:2. See Exhibit E (sequence alignment).

Since the art teaches nucleic acid molecules comprising either 21 or 42 contiguous nucleotides of instant SEQ ID NO:2, it is the Office's position that the nucleic

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acid of art would hybridizes to the complement of instant SEQ ID NO:2. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the two nucleic acid molecules of the prior art do not hybridize to complement of SEQ ID NO:2. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed nucleic acid is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, and 6-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 17-23, 25, 26, 37, and 38 of copending Application No. 10/224,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO:7 in claim 1 of the copending application anticipates instant claim

Art Unit: 1642

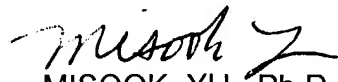
1. Note Exhibit C (sequence alignment). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MISOOK YU, Ph.D.
Examiner
Art Unit 1642

QY	1	GATCAAAGGCGAGGTTCTGAGGAGGCTGCTGCACAAACCAAGCCGGGCGGCTGCTGAGAGG	60
Db	79	GATCAAAGGCGAGGTTCTGAGGAGGCTGCTGCACAAACCAAGCCGGGCGGCTGCTGAGAGG	138
QY	61	GCTGAGCCTGCGGAGACGTGTTCTGTGGGCGAAGCGTGCCCTTCATCAAGACCATCCGGCT	120
Db	139	GCTGAGCCTGCGGAGACGTGTTCTGTGGGCGAAGCGTGCCCTTCATCAAGACCATCCGGCT	198
QY	121	CGTGGGCGCAAGTCGTGCCCTTGCGCCACCGGGAGCCCGATGGCCCTGAGAGGGAGCGCT	180
Db	199	CGTGGGCGCAAGTCGTGCCCTTGCGCCACCGGGAGCCCGATGGCCCTGAGAGGGAGCGCT	258
QY	181	GGCCGCGCGCTGGCCGCCGAGAGAGCTGGCCCTTGAGGCGGAGGTGATCAAAACGGGGGCTT	240
Db	259	GGCCGCGCGCTGGCCGCCGAGAGAGCTGGCCCTTGAGGCGGAGGTGATCAAAACGGGGGCTT	318
QY	241	CCACTGTGCGCATTCGACGTGGA	261
Db	319	CCACTGTGCGCATTCGACGTGGA	339

Exh. b. 14
Page 4

misc_feature

20-1/2. Also called DHR (Dlg homologous region) or GLGF (relatively well conserved tetrapeptide in these domains). Some PDZs have been shown to bind C-terminal polypeptides" /db_xref="CDD:smat00228"
2723..2851
/note="DBE-PR-bind; Region: Phorbol esters/diacylglycerol binding domain (C1 domain). This domain is also known as the Protein kinase C conserved region 1 (C1) domain"
/db_xref="CDD:pfam00130"

ORIGIN

Query Match 100.0%; Score 261; DB 9; Length 3856;
Best Local Similarity 100.0%; Pred. No. 1e-120;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

1 GATCAAGGTGAGGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 60
568 GATCAAGGTGAGGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 627
61 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 120
628 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 687
121 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 180
688 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 747
181 GCCCGCGCGCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 240
748 GCCCGCGCGCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 807
241 CCACCTGGCCATGACGTGGA 261
808 CCACCTGGCCATGACGTGGA 828

RESULT 5

AL359836/c

LOCUS

Human DNA sequence from clone RP11-389B6 on chromosome 10, complete

DEFINITION

AL359836

VERSION

AL359836.16 GI:17977720

KEYWORDS

HTG.

SOURCE

Homo sapiens (human)

ORGANISM

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Homnidae; Homo.

REFERENCE

1 (bases 1 to 49052)

AUTHORS

Smith, M.

TITLE

Direct Submission

JOURNAL

Submitted (21-DEC-2001) Wellcome Trust Sanger Institute, Hinxton, Cambridgeshire CB10 1SA, UK. E-mail enquiries: humgen@sanger.ac.uk

COMMENT

On Dec 23, 2001 this sequence version replaced gi:17984082. During sequence assembly data is compared from overlapping clones. Where differences are found these are annotated as variations together with a note of the overlapping clone name. Note that the variation annotation may not be found in the sequence submission corresponding to the overlapping clone, as we submit sequences with only a small overlap as described above.

This sequence was finished as follows unless otherwise noted: all regions were either double-stranded or sequenced with an alternate chemistry or covered by high quality data (i.e., phred quality >= 30); an attempt was made to resolve all sequencing problems, such as compressions and repeats; all regions were covered by at least one plasmid subclone or more than one M13 subclone; and the assembly was confirmed by restriction digest. The following abbreviations are used to associate primary accession numbers given in the feature table with their source databases: Em, EMBL; Sw, SWISSPROT; Tr, TrEMBL; Wp, WormPep; Information on the WormPep database can be found at http://www.sanger.ac.uk/Projects/C_elegans/wormpep This sequence

was generated from part of bacterial clone contigs of human chromosome 10, constructed by the Sanger Centre Chromosome 10 Mapping Group. Further information can be found at <http://www.sanger.ac.uk/HGP/Chr10> RP11-389B6 is from the library RP11-11.2 constructed by the group of Pieper de Jong. For further details see <http://www.choi.org/bacpac/home.htm> VECTOR: pBAC3.6
IMPORTANT: This sequence is not the entire insert of clone RP11-389B6. It may be shorter because we sequence overlapping sections only once, except for a short overlap. The true left end of clone CTA-109P11 is at 47053 in this sequence. The true right end of clone RP11-129M16 is at 2000 in this sequence.

FEATURES

source

1..49052
/organism="Homo sapiens"
/mol_type="genomic DNA"
/db_xref="taxon:9606"
/chromosome="10"
/clone="RP11-389B6"
/clone_11b="RP11-11.2"

Query Match 100.0%; Score 261; DB 9; Length 49052;
Best Local Similarity 100.0%; Pred. No 8.4e-121;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

ORIGIN

1 GATCAAGGTGAGGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 60
29767 GATCAAGGTGAGGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 29708
61 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 120
29707 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 29648
121 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 180
29647 GCTGAGCCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 29588
181 GCCCGCGCGCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 240
29587 GCCCGCGCGCTGCGGAGAGTCTGAGAGCAGCAAGAGCGCGCGCTGCTGAGAGG 29528
241 CCACCTGGCCATGACGTGGA 261
29527 CCACCTGGCCATGACGTGGA 29507

RESULT 6

AC005887

LOCUS

120578 bp DNA linear PRI 05-NOV-1999

DEFINITION

clb 173.1.12, complete sequence.

AC005887

VERSION

AC005887.3 GI:6249675

KEYWORDS

HTG.

SOURCE

Homo sapiens (human)

ORGANISM

Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Homnidae; Homo.

REFERENCE

1 (bases 1 to 120578)

AUTHORS

Smith, D.R.

TITLE

Sequencing of Human Chromosome 10

JOURNAL

Unpublished

REFERENCE

2 (bases 1 to 120578)

AUTHORS

Smith, D.R.

TITLE

Direct Submission

JOURNAL

Submitted (29-OCT-1998) Genome Therapeutics Corporation, 100 Beaver Street, Waltham, MA 02154, USA

REFERENCE

3 (bases 1 to 120578)

AUTHORS

Smith, D.R.

TITLE

Direct Submission

JOURNAL

Submitted (11-DEC-1998) Genome Therapeutics Corporation, 100 Beaver

REFERENCE 4 (bases 1 to 120578)
AUTHORS Smith, D.R.
TITLE Direct Submission
JOURNAL Submitted (02-MAR-1999) Genome Therapeutics Corporation, 100 Beaver Street, Waltham, MA 02154, USA
REFERENCE 5 (bases 1 to 120578)
AUTHORS Smith, D.R.
TITLE Direct Submission
JOURNAL Submitted (05-NOV-1999) Genome Therapeutics Corporation, 100 Beaver Street, Waltham, MA 02154, USA
REMARK Vector Sequence Clipped
COMMENT On Nov 5, 1999 this sequence version replaced gi:4314331.
FEATURES
source
1. 120578
/organism="Homo sapiens"
/mol_type="genomic DNA"
/db_xref="taxon:9606"
/chromosome="10"
/map="10q25"
/clone_lib="CT987SK-1173112"

ORIGIN

Query Match 100.0%; Score 261; DB 9; Length 120578;
Best Local Similarity 100.0%; Pred. No. 7.8e-121;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGGTGAGTTCAGAGAGCTCTGACAGCAAGACGGCGGGCGCTCTCTGAGGG 60
DB 53976 GATCAAGGTGAGTTCAGAGAGCTCTGACAGCAAGACGGCGGGCGCTCTCTGAGGG 60
QY 61 GCTGAGCTGCGGAGCGTGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 120
DB 54036 GCTGAGCTGCGGAGCGTGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 120
QY 121 CGTGGCGGCAATCGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 180
DB 54096 CGTGGCGGCAATCGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 180
QY 181 GCCCGCGGCTGCGGAGCGTGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 240
DB 54156 GCCCGCGGCTGCGGAGCGTGTCTCTGAGAGCGTGTCTCTGAGAGCAAGACCATCGGCT 240
QY 241 CCACCTGCGCATCGACGCTGGA 261
DB 54216 CCACCTGCGCATCGACGCTGGA 261

RESULT 7
BD169701 3847 bp DNA linear PAT 17-JAN-2003
LOCUS Human glioma antigen and method of preparing the same.
DEFINITION BD169701.1 GI:27875513
ACCESSION WO 02055695-A/6.
VERSION Homo sapiens (human)
KEYWORDS Homo sapiens (human)
SOURCE Homo sapiens
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Homnidae; Homo.
Toda, M., Kawakami, Y., Kawase, T. and Iizuka, Y.
Human glioma antigen and method of preparing the same
Patent: WO 02055695-A 6 18-JUL-2002
KEIO UNIVERSITY, MASAHIRO TODA, YUTAKA KAMAKAMI, TAKESHI KAMASE, YUKIHIKO IIZUKA
YUKIHIKO IIZUKA
OS Homo sapiens (human)
PN WO 02055695-A/6
PD 18-JUL-2002
PE 30-NOV-2001 WO 2001JP010505
PR 09-JAN-2001 JP 01P 001965
PI MASAHIRO TODA, YUTAKA KAMAKAMI, TAKESHI KAMASE, YUKIHIKO IIZUKA
PC C12N15/12 C12N5/10, A01K67/027, A61K31/711, A61K38/00, A61K39/00, A61K39/395,

COMMENT

REFERENCE 8
AC108407/C
LOCUS
DEFINITION Mus musculus clone RP24-422P10, LOW-PASS SEQUENCE SAMPLING.
ACCESSION AC108407.1 GI:18377216
VERSION HTG: HTGS PHASEO.
KEYWORDS Mus musculus (house mouse)
SOURCE
ORGANISM Mus musculus
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Mus.
REFERENCE 1 (bases 1 to 68196)
AUTHORS Birren, B., Linton, L., Nusbaum, C. and Lander, E.
JOURNAL Unpublished
TITLE 2 (bases 1 to 68196)
AUTHORS Birren, B., Linton, L., Nusbaum, C., Lander, E., Ali, A., Allen, N., Brown, A., Camarata, J., Campoliano, A., Chang, J., Chazaro, B., Choquel, L., Collangelo, J., Collins, S., Collymore, A., Cook, A., Cooke, P., Dearellano, K., Dewar, K., Diaz, J. S., Dodge, S., Fero, S., Ferreira, P., Fitzhugh, W., Gage, D., Galagan, J., Gardyna, S., Ginde, S., Gord, S., Royette, M., Graham, L., Grand-Pierre, N., Hagos, B., Horton, J., Hulme, W., Iliev, I., Johnson, R., Jones, C., Kamat, A., Karas, A., Kells, C., Labocque, K., Lamazares, R., Landers, T., Lejczek, J., Levine, R., Liu, G., Maclean, C., MacDonald, P., Major, J., Margulis, N., Matthews, C., McCarthy, M., McGowan, P., McKernan, K., Meldrum, J., Meneus, L., Mihova, T., Mlenga, V., Murphy, T., Naylor, J., Nguyen, C., Nicol, R., Norbu, C., Norman, C. H., O'Connor, T., O'Donnell, P., O'Neill, D., Oliver, J., Peterson, K., Phunhang, P., Pierre, N., Pollara, V., Raymond, C., Retta, R., Rieback, M., Riley, R., Rise, C., Rogov, P., Roman, J., Rosey, P., Spencer, B., Strange-Thomann, S., Schuback, R., Seaman, S., Sever, K., Subramanian, A., Talamas, J., Testaye, S., Theodore, J., Topham, K., Travers, M., Travis, N., Trifillio, J., Vassiliev, G., Vek, R., Vo, A., Wilson, B., Wu, X., Wyman, D., Ye, W. J., Young, G., Zainoun, J., Zembek, L., Zimmer, A. and Zody, M.
Direct Submission
Submitted (27-JAN-2002) Whitehead Institute/MIT Center for Genome Research, 320 Church Street, Cambridge, MA 02141, USA
All repeats were identified using RepeatMasker:
Smit, A. F. A. & Green, P. (1996-1997)
http://ftp.genome.washington.edu/RM/RepeatMasker.html
Genome Center
Center: Whitehead Institute/ MIT Center for Genome Research
Center code: WIBR
Web site: http://www-seq.wi.mit.edu
Contact: sequence.submissions@genome.wi.mit.edu
----- Project Information
Center project name: L18881

FEATURES
source
1. 3847
/organism="Homo sapiens"
/mol_type="genomic DNA"
/db_xref="taxon:9606"

ORIGIN

Query Match 18.0%; Score 47; DB 6; Length 3847;
Best Local Similarity 100.0%; Pred. No. 1e-12;
Matches 47; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 215 GCGGAGGTGAGTACACGCGGCGCTTCCAGCTGCGCATGACGTGGA 261
DB 1 GCGGAGGTGAGTACACGCGGCGCTTCCAGCTGCGCATGACGTGGA 261

COMMENT

CURRENT APPLICATION NUMBER: US/10/224,624
CURRENT FILING DATE: 2002-08-20
PRIOR APPLICATION NUMBER: 60/242,160
PRIOR FILING DATE: 2000-10-20
PRIOR APPLICATION NUMBER: 10/051,769
NUMBER OF SEQ ID NOS: 9
SOFTWARE: PatentIn version 3.1
SEQ ID NO 9
LENGTH: 3465
TYPE: DNA
ORGANISM: Homo sapiens
US-10-224-624-9

Query Match 100.0%; Score 261; DB 15; Length 3465;
Best Local Similarity 100.0%; Pred. No. 2,66-58;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 60
DB 366 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 425
QY 61 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 120
DB 426 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 485
QY 121 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 180
DB 486 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 545
QY 181 GCCCGCGCTGTGGGAGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 240
DB 546 GCCCGCGCTGTGGGAGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 605
QY 241 CCACCTGGCCATCGACGTGGA 261
DB 606 CCACCTGGCCATCGACGTGGA 626

RESULT 9
US-10-112-944-63
Sequence 63, Application US/10112944
Publication No. US20040048249A1
GENERAL INFORMATION:
APPLICANT: Tang, Y. Tom
APPLICANT: Wang, Yonghong
APPLICANT: Wang, Gezhi
APPLICANT: Zhang, Jie
APPLICANT: Ren, Feiyun
APPLICANT: Xue, Aidong J.
APPLICANT: Wang, Jian-Rui
APPLICANT: Whitman, Tom
APPLICANT: Chosh, Malabika
APPLICANT: Wang, Duntui
APPLICANT: Zhao, Qing A.
APPLICANT: Wang, Zhiwei
TITLE OF INVENTION: No. US20040048249A1 Nucleic Acids and
TITLE OF INVENTION: Secreted Polypeptides
FILE REFERENCE: 805A
CURRENT APPLICATION NUMBER: US/10/112,944
CURRENT FILING DATE: 2002-03-28
PRIOR APPLICATION NUMBER: US 09/488,725
PRIOR FILING DATE: 2000-01-21
PRIOR APPLICATION NUMBER: US 09/491,404
PRIOR FILING DATE: 2000-01-25
PRIOR APPLICATION NUMBER: US 09/496,914
PRIOR FILING DATE: 2000-02-03
PRIOR APPLICATION NUMBER: US 09/515,126
PRIOR FILING DATE: 2000-02-28
PRIOR APPLICATION NUMBER: US 09/519,705
PRIOR FILING DATE: 2000-03-07
PRIOR APPLICATION NUMBER: US 09/540,217
PRIOR FILING DATE: 2000-03-31

PRIOR APPLICATION NUMBER: US 09/552,929
PRIOR FILING DATE: 2000-04-18
PRIOR APPLICATION NUMBER: US 09/577,408
PRIOR FILING DATE: 2000-05-18
NUMBER OF SEQ ID NOS: 924
SOFTWARE: pf_fl_genes Version 5.0
SEQ ID NO 63
LENGTH: 3649
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: CDS
LOCATION: (1)..(3462)
US-10-112-944-63

Query Match 100.0%; Score 261; DB 13; Length 3649;
Best Local Similarity 100.0%; Pred. No. 2,66-58;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 60
DB 366 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 425
QY 61 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 120
DB 426 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 485
QY 121 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 180
DB 486 GCTGAGCTGTGGGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 545
QY 181 GCCCGCGCTGTGGGAGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 240
DB 546 GCCCGCGCTGTGGGAGAGAGCTGCTGCGAGAGAGCGGCGCTTCATCAAGACCATCCGGCT 605
QY 241 CCACCTGGCCATCGACGTGGA 261
DB 606 CCACCTGGCCATCGACGTGGA 626

RESULT 10
US-10-224-624-7
Sequence 7, Application US/10224624
Publication No. US20030108915A1
GENERAL INFORMATION:
APPLICANT: McKinnon, Randall D.
TITLE OF INVENTION: Glioblastoma Multiforme Associated Protein GliTen
FILE REFERENCE: 54704.8059 US90
CURRENT APPLICATION NUMBER: US/10/224,624
CURRENT FILING DATE: 2002-08-20
PRIOR APPLICATION NUMBER: 60/242,160
PRIOR FILING DATE: 2000-10-20
PRIOR APPLICATION NUMBER: 10/051,769
PRIOR FILING DATE: 2001-10-20
NUMBER OF SEQ ID NOS: 9
SOFTWARE: PatentIn version 3.1
SEQ ID NO 7
LENGTH: 3832
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: CDS
LOCATION: (178)..(3639)
OTHER INFORMATION:
US-10-224-624-7

Query Match 100.0%; Score 261; DB 15; Length 3832;
Best Local Similarity 100.0%; Pred. No. 2,66-58;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 60
DB 543 GATCAAGTGTGAGTTCAGAGAGCTGCGACACCAAGACCGCGGCGCTGCTGAGGG 602

Exhibit C Page 2 of 2

QY 61 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 120
Db 603 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 662
QY 121 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 180
Db 663 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 722
QY 181 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 240
Db 723 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 782
QY 241 CCACCTGGCCATGACGTGGA 261
Db 783 CCACCTGGCCATGACGTGGA 803

RESULT 11
US-10-276-774-950
Sequence 950, Application US/10276774
Publication No. US20040053245A1
GENERAL INFORMATION:
APPLICANT: Hyseq, Inc.
APPLICANT: Tang, Y, Tom et al
FILE REFERENCE: 21272-030
CURRENT APPLICATION NUMBER: US/10/276,774
PRIOR FILING DATE: 2002-11-18
PRIOR APPLICATION NUMBER: 09/560, 875
PRIOR FILING DATE: 2000-04-27
PRIOR APPLICATION NUMBER: 09/496, 914
NUMBER OF SEQ ID NOS: 2000-02-03
SOFTWARE: Custom
SEQ ID NO 950
LENGTH: 4470
TYPE: DNA
ORGANISM: Homo sapiens
US-10-276-774-950

Query Match 100.0%; Score 261; DB 13; Length 4470;
Best Local Similarity 100.0%; Pred. No. 2.5e-58;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 60
Db 366 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 425
QY 61 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 120
Db 426 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 485
QY 121 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 180
Db 486 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 545
QY 181 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 240
Db 546 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 605
QY 241 CCACCTGGCCATGACGTGGA 261
Db 606 CCACCTGGCCATGACGTGGA 626

RESULT 12
US-10-336-603A-25
Sequence 25, Application US/10336603A
Publication No. US20040072997A1
GENERAL INFORMATION:
APPLICANT: Alsobrook et al.
TITLE OF INVENTION: THERAPEUTIC POLYPEPTIDES, NUCLEIC ACIDS ENCODING SAME, AND METHOD

FILE REFERENCE: 21402-533A
CURRENT APPLICATION NUMBER: US/10/336,603A
CURRENT FILING DATE: 2003-01-03
PRIOR APPLICATION NUMBER: 09/746,491
PRIOR FILING DATE: 2000-12-20
PRIOR APPLICATION NUMBER: 10/055,569
PRIOR FILING DATE: 2001-10-26
NUMBER OF SEQ ID NOS: 169
SOFTWARE: CuraSeqList version 0.1
SEQ ID NO 25
LENGTH: 4801
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: CDS
LOCATION: (178)..(3639)
US-10-336-603A-25

Query Match 100.0%; Score 261; DB 12; Length 4801;
Best Local Similarity 100.0%; Pred. No. 2.5e-58;
Matches 261; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 60
Db 543 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 602
QY 61 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 120
Db 603 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 662
QY 121 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 180
Db 663 GCTGCGGCGAGTGTGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 722
QY 181 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 240
Db 723 GCGCGCGCTGCTGCGGCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 782
QY 241 CCACCTGGCCATGACGTGGA 261
Db 783 CCACCTGGCCATGACGTGGA 803

RESULT 13
US-10-051-769-4
Sequence 4, Application US/10051769
Publication No. US20030044811A1
GENERAL INFORMATION:
APPLICANT: McKinnon, Randy D.
TITLE OF INVENTION: AN EST-DEFINED PROBE FOR CANCER PROGRESSION
FILE REFERENCE: 268/260 (RMT-00-37)
CURRENT APPLICATION NUMBER: US/10/051,769
CURRENT FILING DATE: 2001-10-20
PRIOR APPLICATION NUMBER: US 60/242,160
PRIOR FILING DATE: 2000-10-20
NUMBER OF SEQ ID NOS: 6
SOFTWARE: PatentIn version 3.1
SEQ ID NO 4
LENGTH: 263
TYPE: DNA
ORGANISM: Sprague Dawley rat
US-10-051-769-4

Query Match 79.8%; Score 208.2; DB 15; Length 263;
Best Local Similarity 87.4%; Pred. No. 1.4e-44;
Matches 228; Conservative 0; Mismatches 33; Indels 0; Gaps 0;

QY 1 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 60
Db 1 GATCAAGGTGAGTTCGAGAGCTGCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 60
QY 61 GCTGAGCCTGCGGAGCCTGCTCTGCGGCGAGAGCGGTGCGCTTCATCAAGACCATCCGGCT 120

Exhibit D

APPLICATION NUMBER: US 08/176,427
FILING DATE: 30-DEC-1993
ATTORNEY/AGENT INFORMATION:
NAME: Vincent, Matthew P.
REGISTRATION NUMBER: 36,709
REFERENCE/DOCKET NUMBER: HMT-006CP4
TELECOMMUNICATION INFORMATION:
TELEPHONE: (617) 227-7400
TELEFAX: (617) 227-5941
INFORMATION FOR SEQ ID NO: 6:
SEQUENCE CHARACTERISTICS:
LENGTH: 1425 base pairs
TYPE: nucleic acid
STRANDEDNESS: single
TOPOLOGY: linear
MOLECULE TYPE: cDNA
FEATURE:
NAME/KEY: CDS
LOCATION: 1..1425
SEQUENCE DESCRIPTION: SEQ ID NO: 6:
US-09-736-476-6

Query Match 8.0%; Score 21; DB 1; Length 1576;
Best Local Similarity 100.0%; Pred. No. 0.86;
Matches 21; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 139 CTCGCCACCGGGAGCCCCGA 159
DB 837 CTCGCCACCGGGAGCCCCGA 857

RESULT 15
US-08-748-591-5
Sequence 5, Application US/08748591
Patent No. 5759811
GENERAL INFORMATION:
APPLICANT: Epstein, Ervin
APPLICANT: Hu, Zhilan
APPLICANT: Bonifas, Jeanette
TITLE OF INVENTION: Mutant Human Hedgehog Gene
NUMBER OF SEQUENCES: 23
CORRESPONDENCE ADDRESS:
ADDRESSEE: Fish and Richardson
STREET: 2200 Sand Hill Road
CITY: Menlo Park
STATE: CA
COUNTRY: USA
ZIP: 94025
COMPUTER READABLE FORM:
MEDIUM TYPE: floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
SOFTWARE: Patent Release #1.0, Version #1.25
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/748,591
FILING DATE:
CLASSIFICATION: 435
ATTORNEY/AGENT INFORMATION:
NAME: Sherwood, Pamela J
REGISTRATION NUMBER: 36,677
REFERENCE/DOCKET NUMBER: 06510/067001
TELECOMMUNICATION INFORMATION:
TELEPHONE: (415) 322-5070
TELEFAX: (415) 854-0875
INFORMATION FOR SEQ ID NO: 5:
SEQUENCE CHARACTERISTICS:
LENGTH: 1576 base pairs
TYPE: nucleic acid
STRANDEDNESS: double
TOPOLOGY: linear
MOLECULE TYPE: cDNA
US-08-748-591-5

Query Match 8.0%; Score 21; DB 1; Length 1576;
Best Local Similarity 100.0%; Pred. No. 0.86;
Matches 21; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Search completed: July 18, 2004, 15:54:55
Job time : 58 secs

QY 139 CTCGCCACCGGGAGCCCCGA 159
DB 988 CTCGCCACCGGGAGCCCCGA 1008

LOCUS AM013379 723 bp mRNA linear 3-SEP-10-SEP-1999
 DEFINITION sp042ks winter flounder spleen Pseudopleuronectes americanus cDNA
 sequence.
 accession AM013379
 version AM013379
 keywords EST.
 RCE
 ORGANISM Pseudopleuronectes americanus (winter flounder)
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Actinopterygii; Neopterygii; Teleostei; Euteleostei; Neoteleostei;
 Acanthomorpha; Acanthopterygii; Perciformes; Pleuronectiformes;
 Pleuronectoidae; Pleuronectidae; Pseudopleuronectes.
 1 (bases 1 to 723)
 Douglas, S.E., Gallant, J.W., Bullerwell, C.E., Wolff, C.,
 Munholland, J., and Reich, M.E.
 Winter flounder expressed sequence tags: Establishment of an EST
 database and identification of novel fish genes
 Marine Biotechnology (1999) In press
 Contact: Reich M
 Marine Biology
 NRC Institute for Marine Biosciences
 1411 Oxford St., Halifax, Nova Scotia, B3H 3Z1, Canada
 Tel: (902) 426-8276
 Fax: (902) 426-9413
 Email: michael.reich@nrc.ca
 Seq primer: M13 Forward.
 Location/Qualifiers
 1..723
 /organism="Pseudopleuronectes americanus"
 /mol_type="mRNA"
 /db_xref="taxon:8265"
 /clone="sp042ks"
 /sex="female"
 /dev_stage="adult"
 /clone_lib="Winter flounder spleen"
 /note="Organ: spleen"

IS
 source
 1..723

/organism="Pseudopleuronectes americanus"
 /mol_type="mRNA"
 /db_xref="taxon:8265"
 /clone="sp042ks"
 /sex="female"
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 /note="Organ: spleen"

Query Match 16.1% Score 42; DB 9; Length 723;
 Best Local Similarity 100.0%; Pred. No. 4.2e-08;
 Matches 42; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 GATCAAGTGCAGATTTCAGAGAGCTCTGCGACCAAGACGGC 42
 DB 482 GATCAAGTGCAGATTTCAGAGAGCTCTGCGACCAAGACGGC 523

RESULT 13

LOCUS BB866050 681 bp mRNA linear EST 09-JUL-2003
 DEFINITION BB866050 RIKEN full-length enriched, CRL-1751 WEHI 164 CDNA Mus
 musculus cDNA clone G431003009 5', mRNA sequence.
 accession BB866050
 version BB866050.1 GI:17112260
 keywords EST.
 source Mus musculus (house mouse)
 organism Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Mammalia; Eutheria; Rodentia; Sciurognathi; Muridae; Murinae; Mus.
 1 (bases 1 to 681)

REFERENCE
 AUTHORS Akimura, T., Arakawa, T., Carninci, P., Furuno, M., Hasegaki, T.,
 Hayatsu, N., Hiramoto, K., Hirooka, T., Hirozane, T., Imotani, K.,
 Ishii, Y., Ito, M., Kawai, J., Kojima, Y., Komio, H., Kouda, M.,
 Matsuyama, T., Nakamura, M., Nishi, K., Nomura, K., Numasaki, R.,
 Okazaki, D., Sato, K., Shibata, K., Shinagawa, A., Shiraki, T.,
 Sogabe, Y., Suzuki, H., Tagawa, A., Takahashi, F., Takaku-Kanbara, S.,
 Tanaka, T., Tomaru, A., Toya, T., Watabiki, A., Yasunishi, A.,
 Muramatsu, M., and Hayashizaki, Y.
 RIKEN Encyclopedia of Mouse Full-length CDNA (Akimura, T., et al.
 2001)
 JOURNAL Unpublished (2001)

COMMENT

Contact: Yoshinide Hayashizaki
 Laboratory for Genome Exploration Research Group, RIKEN Genomic
 Sciences Center (GSC), Yokohama Institute
 The Institute of Physical and Chemical Research (RIKEN)
 1-7-22 Suehiro-cho, Tsurumi-ku, Yokohama, Kanagawa 230-0045, Japan
 Tel: 81-45-503-9222
 Fax: 81-45-503-9216
 Email: genome-res@sc.riken.go.jp,
 uni-http://genome.gsc.riken.go.jp/
 Carninci, P., Shibata, Y., Hayatsu, N., Sugahara, Y., Shibata, K.,
 Itoh, M., Komio, H., Okazaki, Y., Muramatsu, M., and Hayashizaki, Y.
 Normalization and subtraction of cap-trapper-selected cDNAs to
 prepare full-length cDNA libraries for rapid discovery of new
 genes. Genome Res. 10 (10), 1617-1630 (2000)
 wagi, K., Fujiwara, S., Inoue, K., Togawa, Y., Izawa, M., Ohara, E.,
 Matabiki, M., Ineda, Y., Ishikawa, T., Ozawa, K., Tanaka, T.,
 Matsura, S., Kawai, J., Okazaki, Y., Muramatsu, M., Inoue, Y., Kita, A.,
 and Hayashizaki, Y.
 RIKEN integrated sequence analysis (RISA) system--384-format
 sequencing pipeline with 384 multichannel sequencer. Genome Res.
 10 (11), 1757-1771 (2000)
 Komio, H., Furumishi, K., Shibata, K., Itoh, M., Carninci, P.,
 Sugahara, Y., and Hayashizaki, Y.
 Computer-based methods for the mouse full-length cDNA
 encyclopedia: real-time sequence clustering for construction of a
 nonredundant cDNA library. Genome Res. 11 (2), 281-289 (2001)
 Please visit our web site (http://genome.gsc.riken.go.jp) for
 e mouse tissues.
 FEATURES
 source
 1..681
 Location/Qualifiers
 1..681
 /organism="Mus musculus"
 /mol_type="mRNA"
 /strain="BALB/c"
 /db_xref="taxon:10090"
 /clone="G431003009"
 /cell_line="CRL-1751 WEHI 164"
 /clone_lib="RIKEN full-length enriched, CRL-1751 WEHI 164
 CDNA"

ORIGIN

Query Match 12.6% Score 33; DB 10; Length 681;
 Best Local Similarity 100.0%; Pred. No. 0.00044;
 Matches 33; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 7 GGTGAGTTTCAGAGAGCTGCTGCGACCAAGAC 39
 DB 565 GGTGAGTTTCAGAGAGCTGCTGCGACCAAGAC 597

RESULT 14

LOCUS BX369637 1079 bp mRNA linear EST 08-MAY-2003
 DEFINITION BX369637 Homo sapiens HECA CELLS COT 25-NORMALIZED Homo sapiens
 cDNA clone CS0K002YA12 5-PRIME, mRNA sequence.
 accession BX369637
 version BX369637.1 GI:30453826
 keywords EST.
 source Homo sapiens (human)
 organism Homo sapiens (human)

REFERENCE
 AUTHORS Akimura, T., Arakawa, T., Carninci, P., Furuno, M., Hasegaki, T.,
 Hayatsu, N., Hiramoto, K., Hirooka, T., Hirozane, T., Imotani, K.,
 Ishii, Y., Ito, M., Kawai, J., Kojima, Y., Komio, H., Kouda, M.,
 Matsuyama, T., Nakamura, M., Nishi, K., Nomura, K., Numasaki, R.,
 Okazaki, D., Sato, K., Shibata, K., Shinagawa, A., Shiraki, T.,
 Sogabe, Y., Suzuki, H., Tagawa, A., Takahashi, F., Takaku-Kanbara, S.,
 Tanaka, T., Tomaru, A., Toya, T., Watabiki, A., Yasunishi, A.,
 Muramatsu, M., and Hayashizaki, Y.
 RIKEN Encyclopedia of Mouse Full-length CDNA (Akimura, T., et al.
 2001)
 JOURNAL Unpublished (2001)

Contact: Genoscope
 Genoscope - Centre National de Sequencage
 BP 191 91006 EVRY cedex - France
 Email: seqref@genoscope.cns.fr Web : www.genoscope.cns.fr
 Library was constructed by Life Technologies, a division of
 Invitrogen. This sequence belongs to sequence cluster 5463.r For
 more information about this cluster, see